K030400 (1 of 2)

DEC 22 2004

510(K) Summary
Preparation Date: August 28, 2003

1.0 Submitter Name and Address

Matt Longson, VP Product Development
NeoSci Medical Inc.
1192 E. Draper Parkway
Suite #442
Draper, Utah 84020

2.0 Contact Person/ Prepared By

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Salt Lake City, UT 84102-1643
801.328.1996 phone / 801.328.2399 fax
philt@philt.com

3.0 Device Identification

Trade Name	Endoluminal Brush
Common Name	Endoluminal Brush Central Venous Catheter Biopsy Brush
Classification Name	Intravascular Catheter Accessory

4.0 **Predicate Device(s)**

Predicate Device Manufacturer / Name

FAS Endoluminal Brush
Digene Cervical Brush
Guidant Hi-Torque Floppy Guide Wire with Hydrocoat Hydrophilic Coating
AngioDynamics Continuous Flush Catheter of its Pulse Spray Infusion System
Galt Medical Guide Wire

5.0 Device Description

The NeoSci Medical (NSM) Endoluminal Brush (EB) is a device similar to a very small diameter bottlebrush that can be inserted into the lumen of partially obstructed central venous catheters to collect a sample. The distal end of the device consists of a flexible tip equivalent to that of a floppy guide wire tip. Immediately proximal to the flexible tip is a segment of bristles wound into flexible, twisted (braided) stainless steel wires. The outer diameter of the bristle profile is selected by the user. Instructions for use recommend that the EB size be 1.2 to 2.0 times the inner diameter of the lumen to be sampled. The stainless steel wires are bonded to a nitinol shaft that extends to the proximal end of the device. The proximal nitinol shaft is encased in a polvtetrafluoroethylene sheath with a hydrophhilic coating applied to reduce friction.

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6.0 Intended Use

The NeoSci Medical Endoluminal brush is intended to collect a sample, which is suitable for microbiological analysis, from the inner lumen surface of an indwelling central venous catheter.

The device is contraindicated for patients with known, or suspected allergies to nitinol, PTFE Teflon®, Nylon, stainless steel, gold or hydrophilic coatings.

7.0 Summary of Technological Characteristics in relation to Predicate Device(s)

Device Component	NeoSci Medical EB	FAS Endoluminal Brush
Distal Tip	Gold-coated tungsten wire wrapped around a central nitinol core	Twisted stainless steel wire loop
Brush Segment	Nylon bristles wound into twisted stainless steel wires	Same design, with different diameter Nylon bristles
Proximal Shaft	Nitinol encased in sheath with hydrophilic coating	Twisted stainless steel wire
Proximal End	Same as proximal shaft	Stainless steel tube bonded to the twisted stainless steel wire, with a loop at the end
Sterile Sheath	None	Clear polymer with PVC Luer lock hubs

8.0 Assessment of Performance Data used to justify Substantial Equivalence Claim

Results indicate that NSM EB Tensile Strength, Torque Strength, Torqueability, Tip Flexibility, Coating Adherence / Integrity, Catheter Compatibility, Biocompatibility, Fracture and Flex Resistance, and Effectiveness of Sampling are suitable for the EB's intended use. Tests were carried out according to protocols based on those identified in ISO 11070, where applicable.

9.0 Conclusion

Performance and safety of the NSM EB meets the relevant requirements for guide wires identified in ISO 11070, and / or are substantially equivalent to the safety and efficacy of the predicate endoluminal brush, and no new issues of safety and efficacy are raised by use of the NSM EB.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2004

Mr. Matt Longson
Vice President Research and Development
NeoSci Medical, Incorporated
1192 E. Draper Parkway
Draper, Utah 84020

Re: K030400
Trade/Device Name: NeoSci Medical Endoluminal Brush
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: December 8, 2004
Received: December 9, 2004

Dear Mr. Longson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

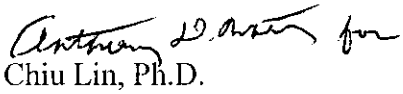
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K030400**

Device Name: **NeoSci Medical Endoluminal Brush**

Indications for Use:

The NeoSci Medical Endoluminal Brush is intended to collect a sample, which is suitable for microbiological analysis, from the inner lumen surface of an indwelling central venous catheter. The proximal nitinol shaft is encased in a polytetrafluoroethylene sheath with a hydrophilic coating applied to reduce friction.

The device is contraindicated for patients with known, or suspected, allergies to nitinol, PTFE Teflon®, Nylon, stainless steel, gold, or hydrophilic coatings.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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